MAIL STOP PCT

Attorney Docket: 26430U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GAU: Unknown

NISHIBE, et al.

Examiner: Unknown

International Application Number: PCT/JP2003/008410

Serial Number: 10/519,484

International Filing Date: 02 July 2003 (02.07.2003)

Filed: December 30, 2004

Title: CICLESONIDE-CONTAINING STERILE AQUEOUS SUSPENSION

TRANSMITTAL LETTER

Commissioner of Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1) Transmittal Letter;
- (2) Information Disclosure Statement;
- (3) PTO Form 1449 with Nine (9) References cited;
- (4) Copies of Nine (9) References cited.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

By:

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: February 24, 2005

NATH & ASSOCIATES PLLC

1030 15th Street N.W., 6th Floor Washington, D.C. 20005-1503

(202) 775-8383

GMN/SMM/le

eary M. Nath

Registration Number 26,965

Sheldon M. McGee

Registration Number 50,454

Customer Number 34375

MAIL STOP PCT

Attorney Docket: 26430U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GAU: Unknown

NISHIBE, et al.

Examiner: Unknown

International Application Number: PCT/JP2003/008410

Serial Number: 10/519,484

International Filing Date: 02 July 2003 (02.07.2003)

Filed: December 30, 2004

Title: CICLESONIDE-CONTAINING STERILE AQUEOUS SUSPENSION

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

- a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- The enclosed statement is being filed after a first] b. action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]: [] i. a certification in part (e) below as specified

in 37 C.F.R. 1.97(e), or

a check in the amount required by 37 C.F.R. ii. 1.17(p).

The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.

[] Certification report(e) below; and

- [] a check in the amount as required by 1.17(p).
-] d. The enclosed statement is being filed pursuant to

Page 2 Attorney Docket: 26430U

37 C.F.R. 1.97(i), for placement in the file.

- [] e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]
- [] I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

[] I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

- [] Appropriate certification is attached.
- [XXX] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.
- [xxx] g. Copies of the documents are attached herewith with a completed Form PTO-1449.

or

[] Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

or

[] Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents

Page 3 Attorney Docket: 26430U

have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: February 24, 2005 By:

NATH & ASSOCIATES PLLC 1030 15th Street N.W., 6th Floor Washington, D.C. 20005-1503 (202) 775-8383 GMN/SMM/le Gary M. Nath

Registration Number 26,965

Sheldon M. McGee

Registration Number 50,454

Customer Number 34375

Page 1 of **1** MAIL STOP PCT Attorney Docket: Serial Number: 26430U 10/519,484 Inventor: NISHIBE, et al. FORM PTO-1449 Filing Date: Group Art Unit: INFORMATION DISCLOSURE CITATION December 30, 2004 Unknown U.S. PATENT DOCUMENTS Examiner Document Sub-Filing Initial Number Issue Date Name Class Class Date Α1 3,962,430 08 Jun. 1976 O'Neill 14 Jul. 1975 FOREIGN PATENT DOCUMENTS Document Sub-Number Date Country Class Class Translation A2 0 233 849 B1 19 Jun. 1991 ΕP N/A A3 62-192322 22 Aug. 1987 JP No 2001-48807 Α4 20 Feb. 2001 JP No 01/28562 A1 26 Apr. 2001 WO N/A A6 01/28563 A1 26 Apr. 2001 WO N/A A7 99/25359 A1 27 May 1999 WO N/A 99/32156 A1 01 Jul. 1999 WO N/A OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Illum, L., et al., "Surface area stability of micronized steroids sterilized by irradiation", Arch. Pharm. Chemi Sci. Ed., Vol. 2, Pp. Α9 167-174, (1974). Examiner Date Considered Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.